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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,239

Applicant(s)

CHANG ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,8,9,12-15,21,30,42-45,47-51,54-62,64-68,70-73 and 75-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-6,30,43-45,47,48,50,54-57,59,64-68,70-73,76-82,90 and 92-94 is/are allowed.
- 6) ☒ Claim(s) 2,3,8,9,12-15,21,42,49,51,58,60-62,75,84-89,91 and 95-98 is/are rejected.
- 7) ☒ Claim(s) 83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of the claims

1. Claims 2-6, 8, 9, 12-15, 21, 30, 42-45, 47-51, 54-62, 64-68, 70-73 and 75-98 are pending.

Applicants' amendment filed June 26, 2003 (Paper No. 19) is acknowledged, and applicant's response has been fully considered. Claims 2, 3, 5, 6, 8, 9, 12-14, 42-45, 47-51, 54-62, 64-68 and 70-73 have been amended, claims 16-20, 46, 53 and 74 have been cancelled, and new claims 76-98 have been added. Therefore, claims 2-6, 8, 9, 12-15, 21, 30, 42-45, 47-51, 54-62, 64-68, 70-73 and 75-98 are examined.

Objection Withdrawn

2. The previous objection to claims 2, 5, 6, 9, 13-15, 42-45, 47-51, 54-62, 64-68, 70-73 and 75 is withdrawn in view of applicant's amendment to the claim in Paper No. 19.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 3 and 8 under 35 USC § 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 14 in Paper No. 19.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 20, 46, 53 and 74 under 35 USC § 102(e), as being anticipated by Wironen *et al.* (U S 2002/0098222 A1, filed March 13, 1997), is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 14 in Paper No. 19.

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5. The previous rejection of claims 16-19 under 35 U.S.C. 102(b) as being anticipated by Gerlach *et al.* (U. S. Patent 5,227,368), is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 14 in Paper No. 19.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 14, 15, 84, 87, 88, 96 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of U. S. Patent 6,413,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14, 15, 84, 87, 88, 96 and 97 in the instant application disclose a recombinant human gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin, which is obtained from one type of collagen. This is obvious in view of claim 29 in the patent which discloses a method of producing gelatin by expressing a DNA encoding a collagen monomer in a host cell. Since DNA encoding human collagen monomer is preferred for the production of gelatin (column 8, lines 3-7), and the limitation of "composition or pharmaceutical composition" in the instant application merely indicates admixing a

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carrier with human gelatin, it would have been *prima facie* obvious to one of ordinary skill in the art at the invention was made, to admix a carrier such as water with the recombinant human gelatin cited in the patent. Therefore, claims 14, 15, 84, 87, 88, 96 and 97 in instant application and claim 29 of U. S. Patent 6,413,742 are obvious variations of a recombinant human gelatin, a composition or a pharmaceutical composition comprising the human gelatin.

6. Claims 14, 15, 84, 87, 88, 96 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of U. S. Patent 6,428,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14, 15, 84, 87, 88, 96 and 97 in the instant application disclose a recombinant human gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin, which is obtained from one type of collagen. This is obvious in view of claim 31 in the patent which discloses a method of producing gelatin by expressing a DNA encoding a collagen monomer in a host cell. Since DNA encoding human collagen monomer is preferred for the production of gelatin (column 8, lines 4-8), and the limitation of "composition or pharmaceutical composition" in the instant application merely indicates admixing a carrier with human gelatin, it would have been *prima facie* obvious to one of ordinary skill in the art at the invention was made, to admix a carrier such as water with the recombinant human gelatin cited in the patent. Therefore, claims 14, 15, 84, 87, 88, 96 and 97 in instant application and claim 31 of U. S. Patent 6,428,978 are obvious variations of a recombinant human gelatin, a composition or a pharmaceutical composition comprising the human gelatin.

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7. Claims 2, 3, 8, 9, 12-14, 21, 61, 75, 84, 87, 88 and 95-98 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12-18 and 47-48 of copending Application No. 10/232,175 (US 2003/0064074). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 3, 8, 9, 12-14, 21, 61, 75, 84 and 95-98 in the instant application disclose a recombinant human gelatin, a recombinant gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin. This is obvious in view of claims 1-7, 12-18 and 47-48 in the co-pending application which discloses a vaccine composition comprising a recombinant gelatin or a recombinant human gelatin, and a method of producing the vaccine composition. Since both the instant application and the co-pending application are directed to a composition comprising the recombinant gelatin. Therefore, claims 2, 3, 8, 9, 12-14, 21, 61, 75, 84 and 95-98 in instant application and claims 1-7, 12-18 and 47-48 of the co-pending application (10/232,175) are obvious variations of a recombinant human gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 88, 89, 97 and 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 88 and 97 are indefinite because of the use of the term "an expression construct". The term "an expression construct" renders the claim indefinite, it is not clear what expression construct is used to produce recombinant human gelatin.

10. Claims 89 and 98 are indefinite because of the use of the term "altered collagen construct". The term "altered collagen construct" renders the claim indefinite, it is not clear what alteration is made in the collagen construct.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Note that patentability of the product by process resides in the product.

Therefore, the product prepared by biochemical purification anticipates the same product produced by recombinant means. In the instant case, the human gelatin indicated in the reference is not distinguishable from the recombinant human gelatin of the claimed invention.

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11. Claims 13-15, 42, 49, 51, 58, 60, 84-87, 91, 95 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Tardy *et al.* (U. S. Patent 5,618,551, April 8, 1997).

Tardy *et al.* teach a powder of non-crosslinked and potentially crosslinkable collagen or gelatin modified by oxidative cleavage (claim 84) and a nontoxic adhesive composition containing reactive acidic solution of collagen or gelatin (column 3, lines 21-77, Examples 1-3), wherein the gelatin is obtained from a heating operation of collagen (column 4, lines 32-34), and collagen can be a human collagen, e.g., enriched human collagen type I, enriched human collagen type III, or enriched human collagen type I + III (column 4, lines 54-59; claims 13-15 and 85-87). The adhesive composition can be used for bonding of biological tissues to one another or in an implanted biomaterial, or stopping bleeding from a biopsy (column 7, line 5-column 8, line 64; claims 42, 49, 51, 58, 60, 91, 95 and 96).

12. Claims 42, 49, 51, 60-62, 84, 87 and 96 are rejected under 35 U.S.C. 102(e) as being anticipated by Wironen *et al.* (U S 2002/0098222 A1, filed March 13, 1997).

Wironen *et al.* disclose a lyophilized gelatin is made from demineralized human cortical bone powder as a source of collagen via pepsin digestion and used in the bone paste composition (Example 1; claims 84, 87 and 96). The composition of gelatin and osteogenic compositions are useful to plug the intramedullary canal of various bones (paragraph 0056, claims 1-2 of Wironen *et al.*; claims 49, 42, 51 and 60-62).

13. Claims 9, 14, 15, 84, 87, 88, 96 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Olson *et al.* (U. S. Patent 6,428,978, priority date, May 8, 1998).

Olson *et al.* teach recombinant gelatin can be produced using constructs encoding a human collagen monomer such as $\alpha 1(I)$ and $\alpha 2(I)$, preferably lacking the C propeptide

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domain and/or the N-propeptide domain in a recombinant host cell (column 8, lines 4-8; claim 31 of the patent; Example 1; claims 14, 15 and 84), and the recombinant collagen is converted to gelatin by thermal denaturation, acid treatment or alkali treatment (column 13, line 66-column 14, line 9; claims 87, 88, 96 and 97). The collagen monomers may be hydroxylated or non-hydroxylated (column 4, lines 24-36; column 6, lines 19-24; claim 9). The composition or pharmaceutical composition merely indicates it contains the human gelatin and a carrier such as water, thus, the claims are anticipated by the reference.

14 Claim 83 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Claims 2, 3, 8, 9, 12-15, 21, 42, 49, 51, 58, 60-62, 75, 84-89, 91 and 95-98 are rejected, claim 83 is objected, and it appears claims 4-6, 30, 43-45, 47, 48, 50, 54-57, 59, 64-68, 70-73, 76-82, 90 and 92-94 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

September 12, 2003

Christopher S. Low
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